



Intro to Health Services

Lesson: April 10, 2020

Learning Target: Understand the drug approval process in the USA



Starter Questions

1. What does FDA stand for?
2. What does the FDA do?



Answer key

1. Food and Drug Administration
2. The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.



Lesson Activity

Go online and research the FDA drug approval process and answer the following on your own paper:

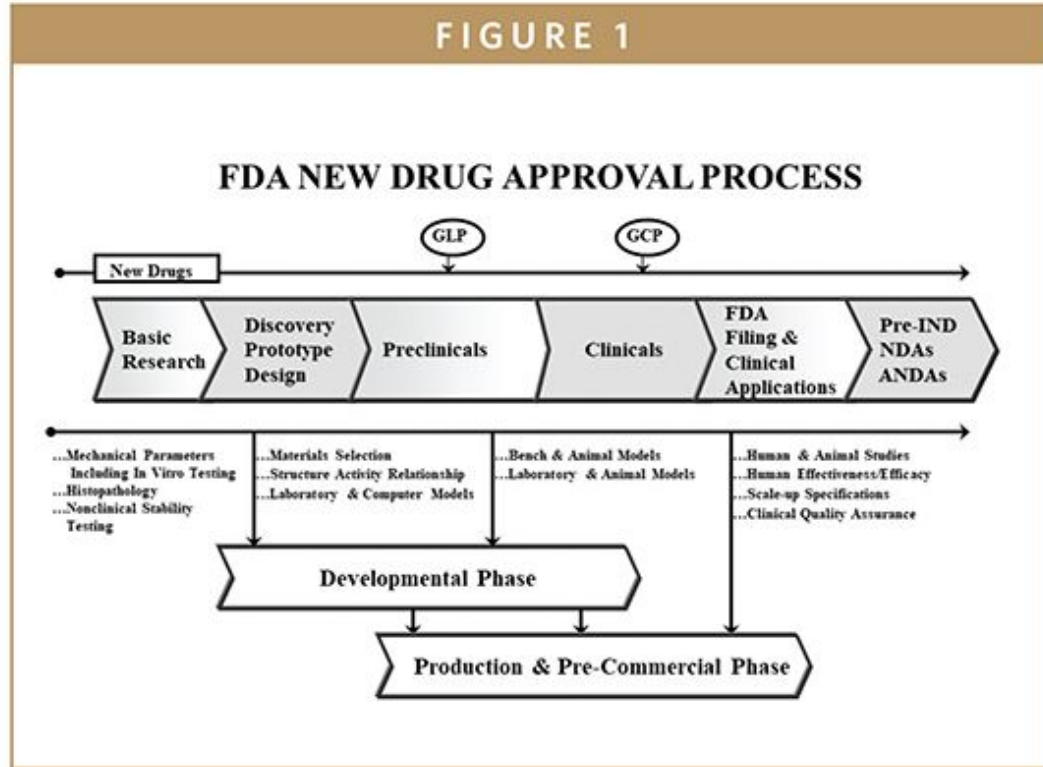
1. How long does it take?
2. What are the steps in the process? List and explain.
3. What companies have to go through this process for their products?
4. What products have to go through the process?
5. What kind of data is needed to prove safety/effectiveness?
6. What is a clinical trial and how many are needed?



Answer key

1. Up to 2.5 years
2. See the picture on the next slide
3. Any company that makes products that go on the skin, in the body, or that put off radiation.
4. Any products that go on the skin, in the body, or that put off radiation.
5. Research studies and clinical trials
6. Anything along the lines of testing on informed patients, multiple

Answer key





More Practice

1. After doing your research, do you feel confident that this process leads to providing the population with safe and effective drugs?
2. Why do you think modern drug commercials have so many legal disclaimers about pre-existing conditions and/or side effects?
3. Why do you think there are so many lawsuits against drug companies if the approval process is so rigorous?
4. What do you think this means for getting a vaccine for the current Coronavirus pandemic (COVID-19)?



Answers will vary